

December 19, 1996

Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell WA 98041-3012

Food and Drug Administr.

Telephone: 205-486-8781 Fax: 206-483-4998

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 97-08

WARNING LETTER

Wayne W. Barker, Co-owner Eileen Barker, Co-owner Barker's Dairy 3130 Aldercrest Road Tillamook, Oregon 97141

Dear Mr. and Mrs. Barker:

An investigation at your dairy operation located at Tillamook, Oregon, conducted on November 20, 1996, confirmed that you offered an animal for sale for food in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

on April 16, 1996, you sold a bull calf, identified with back tag number 92RF7902, for slaughter as human food at USDA analysis of tissue samples collected from this calf identified the presence of 2.5 ppm of gentamicin in the kidney. There has been no tolerance established for residues of gentamicin in edible tissues of calves. The presence of this drug in edible tissues from this calf causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur.

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Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step being taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Richard S. Andros, Compliance Officer, at the above address.

Sincerely yours,

Roger L. Lowell District Director

copy: